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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,460

09/28/2006

Yoko Yamagata

56861

9304

1609

7590

11/09/2011

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.

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WASHINGTON,, DC 20036

EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

11/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,460	Applicant(s) YAMAGATA ET AL.	
	Examiner MICHAEL BURKHART	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1, 7, 8 and 26-28 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1, 7, 8, 26-28 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt and entry of the amendment dated 8/24/2011 is acknowledged.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 7, 8, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elgersma et al (Neuron, 2002), Wang et al (PNAS, 2003), Hanson et al (Neuron, 1994) and Sutoo et al (Brain Res., 2002). **This rejection is maintained for reasons made of record in the Office Actions dated 7/9/2009, 2/18/2010, 6/7/2010, 3/29/2011, and for reasons set forth below.**

Regarding new claims 26-28, these claims are considered to be no different in scope from claims 1, 7 and 8 (see below) as they claim the same structure, i.e. an animal having the same genotype and phenotype. Cytochrome oxidase activity is a general measure of neuronal activity.

Response to Arguments

Applicant's arguments filed 8/24/2011 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the claims recite unexpected results regarding the neuronal and cytochrome oxidase activity.

Regarding 1), this assertion is countered by the facts and results in the prior art. The activity of CaMKII α can be partially supplemented by CaMKII β (Giese et al, page 870, middle column). This may explain why differential effects are found in certain areas of the brain when

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the claimed mutants are used, or it could be that CaMKII α is not required for the measured "neuronal activity" in the cerebral cortex and striatum even though it may be highly expressed in these regions. An example of an unexpected result from using the claimed mice would be that no effects on neuronal activity were found in any part of the CNS, as this would contradict the teachings of the prior art.

Applicants appear to want a 35 USC 102 level of disclosure in the prior art whereas this is a 35 USC 103 rejection. There is always some unpredictability about the outcome of complex experiments, particularly those involving *in vivo* results such as this case. Ample motivation to create the mice has been provided and has not been disputed. Given the totality of the prior art teaching that CaMKIIalpha has a prominent role in neuronal activity and learning, it is not surprising that such a complex and broadly worded phenotype as "neuronal activity" (not far removed from cytochrome oxidase activity, a general measure of neuronal activity) is affected in certain areas of the brain but not others. Further, the recited phenotypes appear to be an inherent result from preparation of the claimed mice in the first place, motivation for which has been provided and has not been disputed. That is, one of skill in the art would have had a strong motivation to prepare the claimed mice regardless of the claimed phenotypes, such phenotypes being inherent results of the genotype (i.e. the K42R mutation in CaMKIIalpha). Applicants assertion of unexpected results is unsupported by any facts or reasoning and is contradicted by the prominent role of CaMKIIalpha in brain and neuronal function as taught by the totality of the prior art.

Double Patenting

Applicant is advised that should claims 1, 7 and 8 be found allowable, claims 26, 27 and 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 26-28 claim a nonhuman animal having the same genotype as those recited in claims 1, 7 and 8, in an apparent attempt to recite a different phenotype. Besides that on first glance this appears impossible in light of the claim language and prior art, there is no indication in the instant specification that animals sharing the same genotype would be distinguishable via the claimed phenotypes. The cytochrome oxidase activity recited in claims 26-28 is taught by the specification and relevant art as nothing more than a general assay for neuronal activity. Thus, the claims do not differ in scope in any significant way.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhardt/
Primary Examiner, Art Unit 1633